



- The Part D benefit is a one-size fits all benefit that *could* disadvantage certain populations
- CMS wanted to ensure that the needs and care of the ESRD population was not adversely affected by this benefit
- CMS also has a need to start thinking about quality and performance





Purpose of the Project

- To establish a baseline of medication use by ESRD dually-enrolled patients
- To identify instances of inappropriate medication use that warrant further review
- To assist in the implementation of the Medicare Modernization Act (MMA) Part D prescription program





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Methods

- Review of Literature
- Analysis of Medication Utilization
 - Data analysis of dually-enrolled ESRD and non-ESRD beneficiaries
 - Demographics
 - Medication prevalence
 - Initial data limited to MS (limits) and AL (no limits) patients—pending national sample
- Review of information and identification of medication issues by technical expert panel (TEP)





Technical Expert Panel

- 12 member panel composed of six MDs, three Pharm.D.s—a transplant recipient/PharmD, and two industry representatives.
- "to assist. . .in determining ESRD specific drug classifications and identifying drugs not recommended for ESRD patients"
- "will assist. . .by proposing criteria which can be used for future development of an ESRD-specific drug utilization review protocol."





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Initial Meeting

- First TEP meeting November 17, 2004.
 - Review literature
 - Comment on the creation of <u>ESRD-specific</u> drug classes, using disease states:

For example:

Hyperlipidemia Bone disease

Hypertension Anemia

■ Comment on a <u>preliminary</u> list of drugs not recommended for ESRD patients





Community Input

- Created "input document" for Renal
 Community based on initial TEP comments
- USP model guidelines released as "input document" was about to be circulated
- In consultation with CMS, "input document" revised and disseminated to the community on March 10





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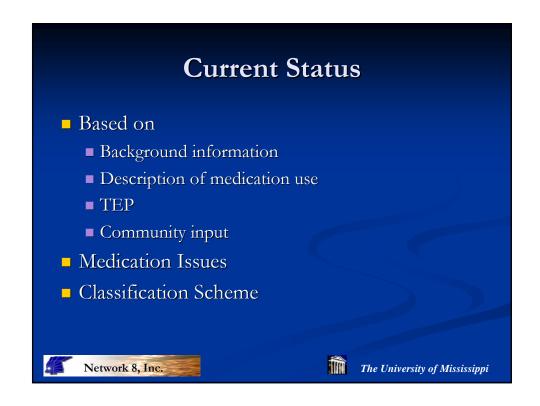
Second TEP

- Second TEP meeting April 13, 2005
 - Review comments from Renal Community
 - Review queries run by UM: drug-drug, drugdisease, prevalence of use of drugs identified at first TEP
 - Based on analyses of medication prevalence within existing classifications, finalize comments on ESRD-specific drug classes

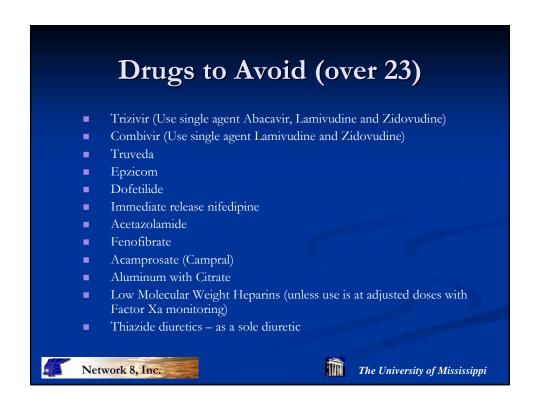




Second TEP Using the USP Guidelines – Provided comments regarding Drugs not appropriate for ESRD patients (AVOID) Drugs that need to always be available (ALWAYS AVAILABLE) Drug classification scheme in light of ESRD patients' needs **The University of Mississippi**



Drugs to Avoid (over 23) Meperidine Ketorolac (Avoid oral) Clavulanate Oxytetracycline Tetracycline Demeclocycline Nitrofurantoin Methenamine Probenecid Ribavirin (Oral) Metformin (and any metformin combination product) Metwork 8, Inc. The University of Mississippi



Always Available

- Based on TEP comments, over 80 medications must always be available to ESRD patients
- Commented on reclassifications of certain medications
 - Calcium Acetate Current USP categorizes as Therapeutic Nutrients/Minerals/Electrolytes
 - Calcium Acetate
 - Gastrointestinal Agents: calcium-containing phosphate binders



Other Comments

- Drug Utilization Review
 - For example:
 - Early refills with phosphate binders, like calcium acetate are a regular occurrence
 - In some instances, greater than usual doses are used



Final Report Report to CMS will: Provide background on the treatment of ESRD Discuss inappropriate medication use Serve as baseline that can be used for determining the impact of medication errors and identification of methods to prevent such Propose medication-related considerations Propose further areas of medication-related investigation Network 8, Inc. The University of Mississippi

